K031211



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# 510(k) Summary of Substantial Equivalence

Date Prepared: April 14, 2003

Submitter: Medtronic, Inc.
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Proprietary Name: Attain™ Prevail® Steerable Catheter Set

Common Name: Catheter, Percutaneous

Device Classification: Class II, 21 CFR § 870.1250

Product Code: 74DQY

## Device Description

The Medtronic Attain™ Prevail® Steerable Catheter Set features a steerable catheter and accessories to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.

The Prevail Steerable Catheter has a single lumen for passage of devices up to 0.035" (0.89 mm) diameter or injection of contrast solutions. Transvenous devices with an inner diameter of 7 French (2.3 mm) or larger can be loaded on and delivered with the Prevail catheter. The catheter features a steerable distal section controlled by the catheter handle. The catheter is radiopaque for visibility under fluoroscopy.

The Prevail Steerable Catheter Set features a guide wire and guide wire torque tool to assist in cannulating the coronary sinus ostium and coronary vasculature. Fluid management components include a Y-connector with an adjustable hemostasis valve, extension tube and 3-way stopcock. The adjustable hemostasis valve is used to reduce blood loss during the procedure. The Y-connector with side port and stopcock are used to aspirate air or inject solutions during the procedure.

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The Prevail Steerable Catheter Set is provided STERILE and is intended for single use only.

## Indications for Use

The Attain Prevail Steerable Catheter Set is indicated to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.

## Substantially Equivalent Devices

| | **Predicate Device** | **Predicate Device Manufacturer** | **Predicate 510(k)** |
|---|---|---|---|
| Percutaneous Catheter | Medtronic Model 10600 Deflectable Catheter System | Medtronic | K013517 |
| | Medtronic Attain LDS Model 6216A Left-Heart Delivery System | Medtronic | K021587 |
| | Medtronic Attain Access Model 6218A Left-Heart Delivery System | Medtronic | K021589 |
| | Medtronic Marinr Series EP Diagnostic Catheters | Medtronic | K931794 |
| | Cardima Naviport Deflectable Guiding Catheter | Cardima Inc. | K974683 |
| Stainless Steel Guidewire | Medtronic AVE Steerable Guidewires | Medtronic AVE | Approved 10/7/86 with P790017/S8 prior to down-classing of PTCA guide wires. |
| Y Connector with Adjustable Hemostasis Valve | Interventional Vascular Y-Adapter | Medtronic AVE | K945461 |
| | Angeion Y-Adaptor with Touhy-Borst Valve | Angeion | K895580 |
| Extension Tubing | Smallbore Extension Set | B Braun | K760385 |
| Stopcock | Medex Stopcock and Luer Lock Plug Model MX531-1L | Medex, Inc. | Pre-amendment device. |
| Guide Wire Torque Tool | Pinvise / Torque Tool | Merit Medical | K921702 (Accessory to Guide Wire) |
| Guide Wire Clip | Class I device, exempt from premarket notification. | | |

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The Attain Prevail Steerable Catheter Set uses similar technology and has similar intended uses, materials and dimensional characteristics to the predicate devices.

## Summary of Studies

Device integrity testing was performed to support the equivalency of the Attain Prevail Steerable Catheter Set to the predicate devices. Testing included mechanical, functional, and packaging testing. The Attain Prevail Steerable Catheter Set met all specified design and performance requirements.

## Biocompatibility Information

Biocompatibility was performed on all blood and tissue contacting materials of the Prevail catheter. Testing performed was consistent with ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". All specified biocompatibility requirements were met.

## Sterilization Validation

The Attain Prevail Steerable Catheter Set will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.

## Conclusion

Through the data and information presented, Medtronic, Inc. considers the Attain Prevail Steerable Catheter Set to be substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Medtronic, Inc.
c/o Lynn Jensen
Cardiac Rhythm Management
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K031211
Attain Prevail Steerable Catheter Set, Model 6228CTH
Regulation Number: 870.1250
Regulation Name: Catheter Percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: May 14, 2003
Received: May 15, 2003

Dear Ms. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

# INDICATIONS FOR USE



510(k) Number (if known): K031211

Device Name: Attain™ Prevail® Steerable Catheter Set

Indications for Use: The Attain™ Prevail® Steerable Catheter Set is indicated to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031211